K062608

510(k) SUMMARY as required by 807.92
Summary of Safety & Effectiveness Information

1. Device Name

SEP 15 2006

Proprietary Name

29 Gauge & 30 Gauge K-Pack II Needle

Classification Name

Hypodermic Single Lumen Needle

21CFR, Section 880.5570

Classification: Class II

2. Reason for Submission

This 510k is being submitted to extend the cleared K-Pack II Needle (K984576) product line. The size of the 29 Gauge needle and the 30 Gauge needle is smaller than what is currently cleared under the current K-Pack II Needle 510k (K984576). This Special 510k is being submitted because of potential issues of safety and effectiveness specific for a smaller/thinner needle. This 510k will provide supporting information that the 29 Gauge & 30 Gauge K-Pack II Needles are safe and effective and an acceptable extension of the current K-Pack II Needle product line.

3. Intended Use

The 29 Gauge & 30 Gauge K-Pack II Needle being Hypodermic Single Lumen Needles are sterile medical devices for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Note: This is the same intended use as the predicate device, K-Pack II Needle – K984576.

4. Description

The 29 Gauge or 30 Gauge K-Pack II Needle is a sterile hypodermic single lumen needle, for single use consisting of a stainless steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polypropylene designed to be connected with a male connector (nozzle) of a piston syringe.

5. Substantial Equivalence

The 29 Gauge and 30 Gauge K-Pack II Needles are substantially equivalent in intended use, design, technology/principal of operation, materials, and performance to the following cleared devices:

1. K-Pack II Needles (K984576)
2. Neolus Needles (K001572)
3. TERUMO 30 Gauge Hypodermic Needle (K012646)

Differences between the devices do not raise any significant issues of safety and effectiveness.

6. Additional Safety Information

The sterility of the 29 Gauge and 30 Gauge K-Pack II Needles is assured by using a validated sterilization method qualified in accordance with EN 550: "Sterilization of Medical Devices: Validation and routine control of ethylene oxide" and ISO 11135: "Medical Devices: Validation and routine control of ethylene oxide sterilization" to a sterility assurance level (SAL) of 10^{-6} as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE" - Part - 1: Requirements for terminally sterilized medical devices".

Ethylene oxide residual levels resulting from EtO sterilization are in compliance with EN ISO 10993-7: " Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals"

The 29 Gauge & 30 Gauge K-Pack II Needle, like the standard K-Pack II Needle (K984576), is an Externally Communicating device, Circulating Blood, Limited Exposure (24 hrs). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and testing".

The expiration dating for the 29 Gauge & 30 Gauge K-Pack II Needle has been established at 5 years which is the same as the cleared K-Pack II Needles.

7. Conclusion

In summary, the 29 Gauge & 30 Gauge K-Pack II Needles are substantially equivalent in intended use, design, technology/principal of operation, materials, and performance to the following cleared devices:

1. K-Pack II Needles (K984576)
2. Neolus Needles (K001572)
3. TERUMO 30 Gauge Hypodermic Needle (K012646)

Differences between the devices do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2006

Mrs. M. J. Aerts
Manager Regulatory Affairs
Terumo Europe N.V.
Researchpark Zone 2 Haasrode
Interleuvenlaan 40
B-3001 LEUVEN-BELGIUM

Re: K062608
Trade/Device Name: 29 Gauge and 30 Gauge K-Pack II Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 31, 2006
Received: September 5, 2006

Dear Mrs. Aerts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

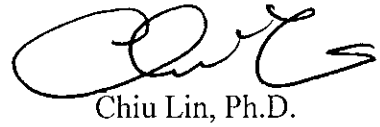
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062608

Device Name: 29 Gauge and 30 Gauge K-Pack II needle

Indications for Use:

The K-Pack II needle being a Hypodermic Single Lumen Needle is a sterile medical device for single use, intended to inject fluids into, or withdraw fluids from parts of the body below the surface of the skin.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...n of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...Number: K962693